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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|--------------------------|------------------|
| 10/053,326 | 01/17/2002 | Satoru Kuhara | JG-YY-4946D/500569.20085 | 4047 |

7590

07/08/2002

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,326

Applicant(s)

KUHARA ET AL.

Examiner

Frank Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 14-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 14-18 and 22-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Rehman *et al.*, (Nucleic Acids Research, 27, 649-655, January 1999).

Regarding claims 14-18 and 22-24, Rehman *et al.*, teach immobilization of acrylamide-modified oligonucleotides on a carrier by co-polymerization. Aliquots of gel solution (0.2 μ l) containing 75% glycerol, 10% total acrylamide (29:1 w/w acrylamide:bis-acrylamide), 5 μ M 5' acryl-amide oligonucleotide, 0.125% w/v APS and 0.125% v/v TEMED were manually pipetted onto silanized glass microscope slides (acrylic silane-treated slides; CEL Associates, Houston, TX). Spotted slides were placed in a humid nitrogen atmosphere at room temperature for 5 min to allow polymerization. Polymerized slide arrays were subjected to electrophoresis in an agarose minigel box (50 mM Tris-acetate, pH 7.8, 2 mM EDTA, 20 V/cm, 20 min) to remove non-immobilized probe. Slides were rinsed in TE buffer or water and dried with a stream of nitrogen as recited in claims 16 (see right column in page 650 and pages 653 and 654, and Figure 6). Note that: (1) the gel solution containing acrylamide (29:1 w/w acrylamide:bis-acrylamide), APS and TEMED could be considered to contain a hydrophilic polymer (polyacrylamide) as recited in claim 14 since APS and TEMED in the gel solution gradually enhanced acrylamide:bis-acrylamide polymerization to form polyacrylamide as recited in claim 24 (containing at least some of polyacrylamide in the gel solution before complete polymerization); (2) since co-polymerization attachment was specific for the terminal acrylamide group of the oligonucleotides (see abstract in page 649, right column in page 651, and Figure 1),

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acrylamide-modified oligonucleotides could be considered to be indirectly fixed to the slide at its one end portion (5' terminus) as recited in claim 15; (3) silanized glass microscope slide could be considered as a glass sheet as recited in claims 17 and 18; and (4) polyacrylamide could be considered as a nonionic hydrophilic polymer as recited in claim 22 (see the specification, page 8, second paragraph) and a cellulose derivative as recited in claim 23 (containing carbon atoms).

Regarding claim 21, 5'-amino oligonucleotide was used in the method recited in claim 1 (see right column in page 651).

Therefore, Rehman *et al.*, teach all limitation recited in claims 14-18 and 21-24.

5. Claim 25 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rehman *et al.*, (January 1999) as applied to claims 14-18 and 21-24 above.

The teachings of Rehman *et al.*, have been summarized previously, *supra*. As shown above, APS and TEMED in the gel solution gradually enhanced acrylamide:bis-acrylamide polymerization to form polyacrylamide. Although one having ordinary skill in the art at the time the invention was made did not know exact concentration of polyacrylamide in the gel solution at each time point before gel complete polymerization, 0.1 to 2% polyacrylamide in the gel solution could be reached at some point during the process of gel polymerization. Therefore, in the absence of convincing evidence to the contrary, the limitation as recited in claim 25 could be considered to be inherent to the reference taught by Rehman *et al.*.

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6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman *et al.*, (January 1999) as applied to claims 14-18 and 21-25 above, and further in view of Brown *et al.*, (US Patent No. 5,807,522, published on September 15, 1998).

The teachings of Rehman *et al.*, have been summarized previously, *supra*.

Rehman *et al.*, do not disclose to spot nucleic acids onto a glass sheet (slide) pretreated with poly-L-lysine as recited in claim 19.

Brown *et al.*, do teach to spot nucleic acids onto a glass sheet pretreated with poly-L-lysine (see columns 16-18).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids onto a glass sheet pretreated with poly-L-lysine in view of the prior art of Rehman *et al.*, and Brown *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Rehman *et al.*, because immobilization of nucleic acids onto a glass sheet pretreated with poly-L-lysine was known in the art at the time the invention was made and the simple replacement of one kind of solid support (i.e., acrylic silane-treated glass slides) from another kind of solid support (i.e., glass slides pretreated with poly-L-lysine) in a method of fixing nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their

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expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman *et al.*, (January 1999) as applied to claims 14-18 and 21-25 above, and further in view of Shi *et al.*, (US Patent No. 5,919,626, published on July 6, 1999).

The teachings of Rehman *et al.*, have been summarized previously, *supra*.

Rehman *et al.*, do not disclose to spot nucleic acids onto a glass sheet (slide) pretreated with a silane coupling agent having an epoxy group as recited in claim 19.

Shi *et al.*, do teach to spot nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group (see columns 8, 14, 15, and 22).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group in view of the prior art of Rehman *et al.*, and Shi *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Rehman *et al.*, because immobilization of nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group was known in the art at the time the invention was made and the simple replacement of one kind of solid support (i.e.,

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acrylic silane-treated glass slides) from another kind of solid support (i.e., glass slides pretreated with a silane coupling agent having an epoxy group) in a method of fixing nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

8. Claims 26 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG

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94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

Frank Lu
June 29, 2002

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.